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Regulating Ozone-Depleting Substances in Ontario:

Sterilants

A Background Report

Program Development Branch
Ministry of Environment and Energy

March, 1994

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R44
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Regulating ozone-depleting
substances in Ontario :
sterilants, a background report.

78471

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Executive Summary

Elimination of ozone-depleting substances (ODS) has recently received the attention for immediate action by the international community. 125 countries, including Canada, have signed the Montreal Protocol and subsequent agreements for phasing-out the production of ODS, including CFCs, by January 1, 1996.

In Canada, with the exception of Ontario, provincial regulations vary from a complete ban on the use of CFC-sterilants to the recovery and recycling of waste sterilants. The latter requires purification and reconstitution to the proper concentrations prior to re-use. This is done in the US.

In British Columbia, the government has offered B.C. hospitals a 60% funding towards the purchase of 30 non-CFC sterilization systems, making B.C. the first province to opt-out of CFC sterilization.

In Ontario, an estimated 330 CFC-sterilization units are in use in Ontario hospitals. No information is currently available on replacing CFC units prior to the phase-out date.

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1.0 Background:

Chlorofluorocarbons (CFCs), organic compounds made up of chlorine, fluorine and carbon atoms, were first developed and introduced in the 1930s as a result of research for safe and efficient refrigerants to replace ammonia. They are mainly non-toxic, non-flammable and chemically-stable. Today, they are also used as solvents in degreasers and cleaners and as diluent of ethylene oxide (EO) used in sterilization of medical equipment.

In the late 1980's, as the dangers of CFCs to the ozone layer in the stratosphere became more apparent, Allied Signal developed a group of substances (hydrochlorofluorocarbons or "HCFCs"), closely related to CFCs but more reactive and hence more prone to natural destruction before reaching the upper atmosphere. They are considered as transitional chemicals since they are a step between ozone-depleting substances (ODS) and non-ODS substitutes.

Medical facilities use CFC-12/88%-EO to sterilize medical equipment such as respiratory equipment, diagnostic instruments and fibre optics. The EO/CFC-12 mixture is used where penetration is needed, where instruments need to be kept sharp (they are dulled by steam autoclaving) and where delicate materials such as plastic and rubber would melt at temperatures achieved in an autoclave.

The purpose of this paper is to introduce the reader to the issue of ozone-depletion, sterilization, the methods used, the chemical substances involved with a special emphasis to CFCs and HCFCs, the environmental case and impact on human health, and to provide options to alleviate the problem.

2.0 The Threat:

2.1 The Environmental Case Against Ozone-Depleting Substances (ODS):

Ozone-depleting substances such as chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) are human produced, fluorine, chlorine and/or bromine-containing organic compounds. When released they slowly migrate to the upper atmosphere (stratosphere) where they undergo photochemical decomposition, releasing highly-reactive chlorine or bromine atoms. These atoms react with other gases including ozone causing a significant reduction in ozone concentration (each atom can undergo 10,000 - 100,000 reactions) before it is stabilized as hydrochloric or hydrobromic acids. Bromine has more destructive power than chlorine.

The presence of one or more hydrogen atoms in HCFCs reduces their stability in the atmosphere; i.e., HCFCs have a shorter life-time which results in reduced destructive ability to the ozone layer.

Other chemicals, such as 1,1,1-trichloroethane (methyl chloroform), and carbon tetrachloride also contribute to ozone depletion.

CFCs also absorb light energy in the infrared region, making CFCs contributors to climate change.

To evaluate the destructive power of an ODS, a measure has been introduced known as the Ozone-Depletion Potential, ODP. It shows how much ozone is destroyed by 1 kilogram of a chemical over a specific period of time. It compares the destructive power of a compound with that of CFC-11 (trichlorofluoromethane) which is given an ODP value of 1.0. [Ref. A Primer on Ozone Deletion, Environment Canada, 30, 1993].

- **Definition:** Ozone Depleting Potential represents the amount of ozone destroyed by emission of a gas over its entire atmospheric lifetime relative to emission of the same mass of CFC-11 (trichlorofluoromethane, lifetime 55 years) which is given an ODP value of 1.0, i.e.
  ODP = Global change in ozone due to an ODS / change in ozone due to CFC-11.

For example, CFC-12 has an ODP of 1.0 and a stratospheric lifetime of 116 years compared with 0.8 and 110 years for CFC-113, 0.6 and 550 years for CFC-115, 0.02 and 129 years for HCFC-124, 0.02 and 47 years for HCFC-123, and, 0.11 and 76 years for HCFC-141b.

Recent data show that the concentration of chlorine in the stratosphere has increased from 1.5 ppbv in 1970 (part per billion by volume) to 2.5 in 1980 and 3.6 in 1991.

Ozone-depletion allows increased levels of UV-B radiation to reach the earth's surface. The environmental impact is the risk of loss of phytoplankton (microscopic marine plant life) responsible for storage of 80% of carbon dioxide leading to enhancing greenhouse gases and global warming. In addition, cloud patterns may also be affected by phytoplankton losses.

The economic impact of UV-B radiation environmental damage to plastic and wood construction materials and forestry could be significant.

2.2 Effects of Ozone-Depletion on Life and Human Health:

The increase in UV-B radiation can cause adverse effects on plants, insects, birds, fish and animals. Decreased growth of fruits, vegetables and trees has also been reported. Skin cancer and eye tumours due to UV-B exposure were observed in domestic animals.

Human exposure to UV-B radiation may cause eye damage leading to the development of cataracts. 10% thinning of the ozone layer will result in an estimated 2 million new cases of cataracts globally.

It was reported [*] that UV-B radiation weakens the immune system and reduces the body's ability against infections. Furthermore, extensive exposure to UV-B radiation increases the risk of developing skin cancer. [*] Ref. Canadian Cancer Statistics, 1992.

Recent studies in Canada show that approximately 50,000 new cases of skin cancer were expected in 1992 as a result of exposure to UV-B radiation. Out of these new cases of skin cancer, 3100 are lethal (melanoma) and 570 resulted in death, making skin cancer the fastest growing cancer. The cost of skin cancer treatment in 1992 was estimated at $50 million.

3.0 Methods of Sterilization:

Several methods are currently available for sterilization purposes. In Canada, steam, 100% ethylene oxide and 12% ethylene oxide/88%CFC-12 sterilization are used in hospitals and medical institutions. Hospitals may realize the potential benefits and savings resulting from streamlining their operations by using non-CFC techniques at their maximum potentials, and by reducing the dependence on EO/CFC-12 sterilization.

In the USA, of all the quantities of ethylene oxide used in commercial sterilization in 1986, 30% was used in EO/CFC-12 blends, 60% for EO sterilant, and 10% in other mixtures. Steam is widely used in both hospitals and by manufacturers for sterilization of non-heat sensitive products.

Overseas, several european countries do not use EO/CFC-12 in hospitals. In Germany, the use of all types of EO sterilants is limited due to occupational health and safety concerns. New regulation with restrictions on emissions of EO will further limit its use. Instead, in Germany and the Nordic countries, steam and formaldehyde sterilization are mainly used. Some hospitals use 100% EO for sterilization of heat and moisture-sensitive devices.

Formaldehyde is currently used in the UK with increased interest in Eastern Europe and the Middle East. 100% EO is also used in the UK and Italy, while EO/CFC-12 is widely used in France and Belgium. Little is known about sterilization in East European countries.

The dependence of developing countries on imported 12/88 sterilants will likely result in their conversion to 100% EO or HCFC blends as the supply of CFC-12 is greatly reduced.

The following is a summary of the available sterilization methods.

3.1. Ethylene Oxide (EO) and EO/CFC-12 Sterilization:

Ethylene oxide (EO) gas is accountable for the sterilization process. It has the ability to penetrate a wide variety of packaging materials to destroy micro-organisms on medical products and devices. EO is particularly useful in sterilizing heat and moisture-sensitive equipment. Due to its properties, the sterile integrity is maintained during handling, storage and transport of medical equipment prior to use.

Ethylene oxide itself is toxic, mutagenic, a suspected carcinogen, flammable and explosive. For these reasons, EO is usually diluted by mixing it with CFC-12 (dichlorodifluoromethane) in a ratio of 12% EO and 88% CFC-12. This mixture is usually known as 12/88. Other gases such as carbon dioxide or nitrogen can be used as diluents. 90% of the former is mixed with 10% EO to produce the sterilant gas, and the mixture is known as 10/90.

Sterilization is carried out above atmospheric pressure in specially designed equipment by experienced personnel. Since both EO and the diluent gas are volatile, they are easily removed by aeration from the sterile equipment usually at elevated temperatures.

The process of sterilization with EO or 12/88 can be summarized as:
- temperature and moisture conditioning;
- introduction of sterilant mixture
- sterilization period
- aeration of sterilized equipment using carbon dioxide or nitrogen.

100% EO has been safely used by manufacturers of medical equipment under stringent storage and operating conditions. However, conversion of EO/CFC-12 systems to 100% EO requires extensive retrofit costs.

New sterilization systems using 100% EO cartridges are now available where small quantities of EO are used with reduced risk of fire or explosion. The systems can also be provided with catalytic converters to convert the waste into carbon dioxide and water prior to its release into the atmosphere.

HCFC-123, HCFC-124, HCFC-125, HCFC-141b, HCFC-152a, HFC-134a, and HFC-227ea are presently promoted as alternatives to CFC-12 diluent to EO. The blends are particularly attractive as transitional drop-in alternatives. However, HCFCs, while they have a comparatively lower ozone-depleting potential, they are also destined for a phase-out according to the Montreal Protocol. Use of HCFCs must be discouraged to ensure that they will be capped in 1996 at a level equal to the ODP-weighted 1989 consumption plus 3.1% of the ODP-weighted CFC consumption. HCFCs will be phsed-out gradually (35% by 2004, and 99.5% by 2020. Increased demand for HCFCs may cause increased operational costs.

3.2 Steam Sterilization:

Steam sterilization is accepted world-wide as an economical, non-toxic and safe method for all medical devices that can withstand a temperature of 121°C and high moisture. Steam is not an alternative to EO/CFC-12 for sterilization of equipment such as pace-makers and catheters that cannot withstand high temperatures. However, the method can be particularly attractive in reducing the need for EO by selective operating sterilization practices and limiting EO to the most needed requirements.

3.3 Formaldehyde Sterilization:

Formaldehyde is used as a sterilant of devices that can withstand high humidity and a temperature of 80-85°C. Packaging materials should be selected to allow the vapours to reach the devices.

Formaldehyde is toxic, a suspected carcinogen and has an irritating odour. It is widely used in Europe for equipment that cannot be sterilized by steam. However, it is not an attractive alternative to EO in the USA, mainly for occupational exposure concerns.

3.4 Ethylene Oxide (EO)/Carbon Dioxide (CO_2) Sterilization:

EO-CO_2 mixtures in concentrations of 10/90% are used as sterilants. Other blends (15/85%) are commonly used in Europe. Sterilization vessels with higher pressure rating may be necessary.

Because of the differential vapour pressures of EO and CO_2 and preferential vaporization of the latter into the headspace in gas cylinders, an enriched EO mixture results as the cylinder is emptied. This problem causes uncertainty of sterilization and increases the risk of explosion. Single charge cartridges may alleviate this problem.

The advantage of this method is the minimal cost of conversion of EO/CFC-12 systems into 10/90 without compromising the integrity of sterilization or damaging the ozone layer.

3.5 Radiation Sterilization:

Isotope and electron beam sterilization are mainly used by manufacturers of medical devices, especially single use products. Limitations of the isotope procedure are the high initial capital costs and the problem of disposal of radioactive waste. Currently, there are only a few electron beam sterilization units in use.

3.6 Dry Heat Sterilization:

The method is used for sterilization of objects that can withstand temperatures about 190°C. The main drawback is that sterility cannot be maintained and equipment must be used immediately.

3.7 Peracetic Acid Sterilization:

Peracetic acid is an effective wet sterilant and, therefore, has limited applications. However, a new sterilization system that uses a blend of argon, hydrogen, oxygen and peracetic acid was introduced to the market in 1993. Thirty units have been purchased and are currently being installed in British Columbia hospitals.

3.8 Chlorine Dioxide (ClO_2) Sterilization:

A sterilization process using gaseous chlorine dioxide is currently under development. The process is being tested on specific devices in an industrial environment and applications in hospitals may be possible in the future. ClO_2 may be adapted to existing EO sterilizers.

Unlike 12/88 blends, ClO_2 is unstable and must be generated on-site. It is a hazardous agent that decomposes spontaneously at elevated concentrations and temperatures.

The problem of product compatibility and the ability of the sterilant to penetrate packaging materials are potential disadvantages. Because its reactive oxidizing nature, ClO_2 may bleach and thus degrade product and packaging materials. Only glass can be sterilized. Respectively, plastics life-time is reduced as chlorine reacts with plastic making it brittle and weak.

The technology does not appear at this time to be a broad-scale replacement of EO. [Ref. Aerosol Products, Sterilants, Miscellaneous Uses, and Carbon Tetrachloride; a UNIP report by the Technical Options Committee, December, 1991].

3.9 Gaseous Ozone Sterilization:

Ozone is an effective sterilant. However, its use is limited since a very few medical devices can withstand its strong oxidising properties.

3.10 Hydrogen Peroxide (H_2O_2) Sterilization:

At least one sterilization system using hydrogen peroxide has received FDA approval in the USA. It is an effective ozone-friendly sterilant and turns into oxygen and water after sterilization. The relatively fast turnaround sterilization time and lower cost of operation make it an attractive sterilization alternative.

3.11 Gas Plasma Sterilization:

Sterilization is achieved by introducing the medical equipment into a high vacuum chamber and then subjected to ionized gas plasma created by a radio-frequency field. If compatible packaging materials are used, the system can be at least a partial replacement for EO/CFC-12 sterilants.

Since hydrogen peroxide is used as a seeding agent for plasma generation, the end product is water and oxygen making it an environmentally-friendly alternative.
Tables 1.a, 1.b and 1.c present a summary of the commercially available sterilization systems, the sterilants used and their suppliers.

Table 1.a: Description of Sterilization Systems, their uses, and potential substitutes.

Commercial Name	Description	Supplier
Abtox Plazlyte Sterilization System	- low temperature Gas Plasma Sterilization	Distributor: Ingram & Bell Ltd., Canada - Manufactured in USA
STERRAD Sterilization System	- low temperature Gas Plasma Sterilization using H_2O_2	Distributor: Johnson & Johnson Medical Products - Manufactured in USA
Steris Sterilization System	- low temperature sterilization unit using Peracetic acid	Distributor: Ultramed, Canada - Manufactured in USA
VHP Series 100 Cassette Sterilizer	- low temperature vapour phase sterilization unit using H_2O_2	Distributor: AMSCO Canada - Manufactured in USA
Steri-Vac Sterilizer	- low temperature sterilization unit using 100% ethylene oxide gas cartridges	
EO-Abator System	- removes EO from the air stream exhausted from Steri-Vac Sterilizer	
GEE Sterilizers	using 10% EO/90% CO_2 gas mixtures, 100% EO or HCFC-124 with integrated EO removal from exhaust	Distributor: Getinge, Canada - Manufactured in Sweden

Table 1.b

Commercial Name	Description	Supplier
MDT Castle Sterilizers	- presently using 12/88 mixture offering conversions to: a) 8.6% EO/91.4% HCFC (oxyfume 2000) b) 7% EO/93% CO_2	Manufactured by Praxair, Distributed by: Medi Gas Canada Manufactured by Canadian Liquid Air Ltd., Canada
AMSCO STERILIZERS	- presently using 12/88 mixture offering conversion to 8.6% EO/91.4% HCFC	AMSCO manufacturing in USA
CFC/HCFC/EO Capture and Recycling Technology	- removes gases from exhaust and converts emissions for regeneration	Linde, Canada and MG Industries, Canada
Gamma Sterilization	- used since 1978 in commercial installations. Considered by some for centralized hospital processing site.	
Ultraviolet Radiation	- Applicable for surface sterilization only, not medical devices packaged in various materials.	- Culligan of Canada Ltd. - Evergreen Equipment Ltd.
Low-Temperature Steam Formaldehyde	- used in Europe, concern about residuals in sterilized materials and for occupational exposure	
Ozone	- gas sterilization unit using ozone converted from oxygen	Manufactured in USA Not in Canada at present

Table 1.c

Commercial Name	Description	Supplier
Oxyfume HCFC-124	- Diluent	- Joslyn Sterlizer Corp.
HFC-134a	- Diluent	- ICI Canada Inc.
12/88	- Recovery & Recycling Sterilizers	- Joslyn Valve Corp. - Chemrox - MG Industries - Union Carbide
Steam Sterilization	- Autoclaves	- American Autoclave Co.
Dry Heat	- High temperatures	- Stainless Steel Industries Ltd.
Gluter Aldehyde	- CIDEX - Coldspar - Sporicidin - Metrozyme	- Johnson & Johnson Research - Metrax Research Corp. - Medical Mart - Medical Mart - Henckel Medical Supply
Pasteurization	- 100% EO - pre-sterilized disposable devices - low temperature glow plasma & H_2O_2	- Union Carbide
Castle Sterilizer	- CO_2/EO - 10/90 - CO_2 peracetic acid	- MDT CORP. - Fryston Canada Inc.
MP33	- Blend of R-22, HCFC-152a, HCFC-124	- DuPont

4.0 Economic Implications of Sterilization Technologies:

The markets for sterilants are characterized in terms of firms that produce and distribute sterilant gas mixtures and associated sterilizing equipment and the users of sterilants and equipment. Information about alternative sterilizing compounds, equipment, technologies and systems that can be used in place of 12/88 mixture are assembled in order to forecast the responses of stakeholders to the various Regulatory Options. The relative costs of alternative sterilization techniques are summarized in Table 2 below.

4.1 Market Structure:

CFC-12 is no longer produced in Canada. Consequently, all CFCs destined for the production of sterilants are imported from the U.S.A. where they are manufactured by major chemical producers such as Dupont or Allied-Signal.

In Ontario, CFC-12 is blended with ethylene oxide to make EO/CFC-12/88 by firms such as Praxair and Canadian Liquid Air. Praxair apparently has an agreement with Steriteck (a sterilizer equipment company) to recover and process used 12/88. Users would receive credit from Praxair toward future gas purchases. Reprocessing of used 12/88 is done in the U.S.A.

These blenders either sell sterilant blends directly to users or to distributors such as Medigas or Liquid Carbonic who in turn sell the gas to users.

Users of sterilants include hospitals (which account for almost 98% of the total number of sterilizers in the province), pharmaceutical companies, private and provincial medical labs and a veterinary hospital in Guelph.

Several firms sell sterilization equipment in Ontario, all of which are imported, that use 12/88: AMSCO, MDT Corp., 3M, Johnson & Johnson, Joslyn Sterilization Corp. and Getinge Canada.

The following companies distribute sterilant systems: Ingram and Bell (on behalf of ABTOX Corp.), Ultramed Canada, and Johnson & Johnson. Steriteck produces sterilant gas recovery equipment and processes used gas for resale.

Ethylene oxide is produced in Canada by Dow Chemical although 90% of EO production is used to make ethylene glycol, an antifreeze.

An important constraint on the selection of non-ODS sterilants is to maintain existing sterilization standards.

4.2 Costs of Alternative Sterilant Chemicals and Technologies:

There are a number of alternatives to 12/88 sterilization. However, there is no "perfect substitute". Costs - operating and capital - are identified (where available) below.

- The Gas Plasma alternative requires the purchase of a new sterilizing unit. The price of the unit is approximately $120,000, while the price of the sterilant is approximately $4 per ft^3 load. The producer Ingram & Bell started selling both items in November, 1993.

- Ultramed Canada has developed "Steris Sterilization System". The system is manufactured in the U.S. The price for a 2 ft^3 machine is about $27,000. This machine sterilizes using alkaline buffing agents, water, and peracetic acid. The cost per ft^3 is about $5. After sterilization, the used sterilant turns into a liquid similar to vinegar and is discarded into the sewer system.

- Johnson & Johnson is marketing the "Sterrad Sterilization System". It costs $145,000 per unit, with an operating cost of $4 per ft^3. This system is manufactured in the U.S.. It is the first system to be FDA approved. It was to be released in November 1993. This system uses hydrogen peroxide (HP), which is turned from a gas into gas plasma. A byproduct of the gas plasma, called "free radicals", kills bacteria. This system does not need to be ventilated or monitored, thus, instruments can be sterilized quickly (within 75 minutes).

  However, this system is not compatible with paper, linen and cotton wraps (i.e., it is not capable of sterilizing through these materials). It will sterilize through a polyethylene wrap. This system has been purchased by Peterborough Civic Hospital and Ottawa General Hospital.

- The 100% EO alternative requires the purchase of a new EO sterilizer. The only sizes available are 4 to 5 ft^3 units, which are called "table top" sterilizers. The price of this sterilizer is $35,000, with an additional $5,000 installation fee and an operating cost of $2 per ft^3. A hospital with high sterilization demands, if converting, would have to buy many of these table top sterilizers to meet its sterilization needs.

There exist two options to retrofit existing 12/88 sterilizers:

- Oxyfume 2000 (HCFC-124/EO) which costs approximately $7.50 per pound can be used in a retrofitted Castle sterilizer machine. The cost to retrofit is about $100. It can also be used in a retrofitted AMSCO sterilizer. Retrofit cost is about $2,000.

- 10/90 (EO/CO_2) which cost approximately $1.50 per pound can be used in a retrofitted Castle sterilizer machine. The cost to retrofit is about $17,000 to $18,000. This blend can not be used in an AMSCO sterilizer machine.

Table 2: Sterilization Techniques: Alternatives to 12/88

TECHNIQUES/SYSTEMS	COST RELATIVE 12/88	SUITABLE FOR HEAT-SENSITIVE EQUIPMENT	TOXICITY	FLAMMABLE	COMMENTS
Steam	Lower	No	No	No	lowest cost sterilization method
Formaldehyde	Lower	Yes	Acute and carcinogenic	No	use restricted in some countries
Ethylene Oxide	Higher	Yes	Acute	Yes	high conversion costs; safety procedures are essential
10/90	Higher	Yes	Acute	No	operating problems
Radiation	Higher	Yes	No	No	safety procedures essential; radioactive wastes problems
Dry Heat	Lower	No	No	No	sterilized equipment must be used immediately
Oxyfume 2000 (EO/HCFC 124)	Higher	Yes	Acute	No	"drop-in" replacement for 12/88; considered an ozone-depleting substance

SOURCE: Protecting the Ozone Layer, Volume 5: Aerosols, sterilants, carbon tetrachloride and miscellaneous uses. [United Nations Environment Program]

5.0 Regulatory Activity in Other Jurisdictions:

Governments around the world recognize the threat posed by stratospheric ozone-depletion. There is a wide agreement among 125 countries signatories to the Montreal Protocol that the production and use of ozone-depleting substances must be phased-out.

Some countries such as Switzerland, Sweden, Germany, Denmark, Australia, the Netherlands, the United States, Canada and members of the European Community are phasing-out ODS faster than required by the Montreal Protocol schedules.

Members of the European Free Trade Agreement (EFTA) have also adopted measures to meet or exceed the Protocol requirements.

5.1 International Agreements to Phase-out CFCs:

Negotiations by the *United Nations Environment Program* (UNEP) resulted in the *Vienna Convention* for the protection of the ozone layer, March 1985. The Convention provided a framework for international cooperation in research, environmental monitoring and information exchange. In September 1987, 24 nations signed the *Montreal Protocol* on ozone-depleting substances (ODS). As of September 1991, this number has increased to 75 nations and was geared towards limiting the production, import and export of specific CFCs.

Definitions:
Consumption = production + import - export
Production = amount produced - amount stored - amount of feedstock used to produce other substances
Note: The amount recycled is not considered "production".

In June 1990, parties to *Montreal Protocol* met in London and agreed to more stringent controls on ODS in the original Protocol and added other ODS including carbon tetrachloride and methyl chloroform. The *London Amendments* to the *Montreal Protocol* have entered into force on August 10, 1992.

The *Copenhagen Amendments* , Table 3, to the *Montreal Protocol* have entered into force on September 22, 1992.

According to the *Copenhagen Amendments*, the deadline for phase-out of CFCs was advanced to January 1, 1996, with a 75% reduction set for January 1, 1994. Methyl chloroform and carbon tetrachloride will be phased-out by January 1, 1996. HCFC will be capped in 1996 at the 1989 level with a 35% reduction by 2004, 65% by 2010, 90% by 2015 and a complete phase-out by 2030. Parties to the Protocol are also encouraged to reduce the use of HCFCs to essentials. Advancement of the phase-out date cannot be ruled out.

Parties to the Montreal Protocol recognize the importance of a commitment from the international community to control ozone-depleting substances. Hitherto, none of the 125 parties to the Protocol including the USA has requested an essential exemption for sterilization.

However, not all nations were signatories to the Montreal Protocol or committed to its implementation (e.g., Russia and some East European countries). Subsequent meetings were held to reaffirm commitments, to add new substances to the list of those being restricted and to set additional deadlines.

A special fund, Multilateral Fund, in the amount of $240 million over three years was created to assist the developing countries in covering the new cost and will encourage others to join the effort.

Table 3: Synopsis of Negotiated Reductions in Ozone Depleting Substances - Copenhagen Amendments:

Year	**CFCs**	**Halons**	**MCF**	**CTC**	**Methyl Bromide**	**HCFCs**
1994	75% cut	100% cut	50% cut			
1995				85% cut	cap	
1996	100% cut		100% cut	100% cut		cap
2004						35% cut

5.2 Regulatory Activity in the United States:

The United States federal government implemented an excise tax on ODS in 1989. It was intended to tax windfall profits to producers that would result from rising prices as ODS production was curtailed. The tax is calculated by multiplying a tax rate specified for each type of ODS by the ozone-depletion factor, then multiplied by the pounds of each ODS sold by manufacturers or importers. The system is complicated by exemptions for ODSs used in feedstock where the chemical is consumed entirely or recovered for reuse. These taxes are paid annually and are expected to generate between $500 million and $1 billion per year.

The US-EPA is working with the Industry Cooperative for Ozone Layer Protection (ICOLP) to provide technical information and manuals on ODS alternatives including CFCs. In addition, the EPA requires the labelling of products that contain, or were manufactured with Class

I or Class II ODS and containers in which these substances have been purchased or stored (Section 611 of the Clean Air Act).

The 1990 EPA data on CFC-12 consumption in the U.S.A. show that less than 4% was used in sterilant blends, mainly by hospitals. 100% EO was the preferred option by the sterilization industry.

The EPA has recently (May 1993) approved carbon dioxide as a substitute for CFC-12 and HCFC-124 as a transitional alternative. A sterilant blend of HCFCs and HFCs is currently under consideration for approval.

The final US-EPA ruling (FRL-4810-7) reported in December, 1993 sets the quantities apportioned to producers and importers of the controlled ozone-depleting substances including CFC-12.

The EPA compliance and control procedures include the requirement for an application for consumption documenting the users, name and quantity of substance, quantity transformed or destroyed and the efficiency of the destruction process.

5.3 Regulatory Activity of the Government of Canada:

Legislative action in Canada and elsewhere have been prompted by the **Montreal Protocol** which was signed in 1987. The signatories, including Canada, agreed to specific reductions in the production (and by implication, release) of ODS by certain dates. For example, governments agreed to eliminate production and consumption of CFCs by 1996, but with certain exemptions that would allow production or import for "essential uses" which are determined by an international technology and economic assessment panel.

For example, in November 1992, Canada and other parties to the Montreal Protocol agreed to new phase-out dates for CFCs, carbon tetrachloride, methyl chloroform, halons, HCFCs, HBFCs and methyl bromide. These nations further agreed to reduce production of HCFCs by 90% of the 1986 levels by 2015 and their total elimination of these chemicals by 2030.

To implement these agreements in the time frames specified, individual jurisdictions must enact legislation or regulations under existing legislations. The government of Canada has promulgated four regulations under the Canadian Environmental Protection Act which sets out command and control restrictions on the amount of CFC's that can be imported or manufactured in Canada.

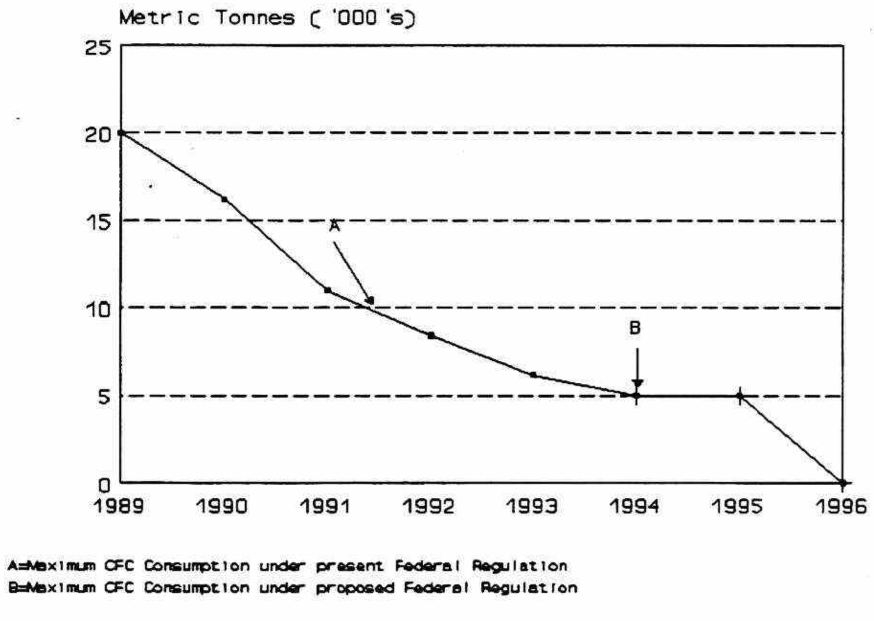
Federal Regulation No. 1 restricts the manufacture and import of CFCs to the "actual aggregate weighed quantity" manufactured and imported during the preceding years starting in 1989. Imports can only come from countries that are participants of the Montreal Protocol.

The Canadian federal government is developing a new command and control regulation that is intended to:

- require a 75% reduction in the production, import and export of CFCs by January 1, 1994;
- require a 100% reduction on production, import and export of CFCs by January 1, 1996.

The proposed federal regulation does not place any restrictions on the use of CFCs. This means that CFCs already manufactured and in use in Canada can continue to be used and will ultimately be released to the atmosphere. The current federal regulations are being consolidated and the phase-out schedule will be accelerated to reflect amendments to the Montreal Protocol.

Figure 1 illustrates the estimated quantities of CFC consumption between 1989 and 1994 under the existing federal regulation and what is expected between 1994 and 1996 if the proposed federal regulation is promulgated.



SOURCE: Environment Canada

Fig. 1 Current and Proposed Federal Regulations on CFCs

5.4 Regulatory Activities in Other Provinces:

Alberta:

The Alberta regulation states that effective September 1, 1993, a general prohibition was put in-place on the manufacture, offer for sale, sale, or, except where permitted, release of ozone-depleting substances into the ambient air. Exemptions from the prohibition include the use of ODS for human and animal health care applications including sterilization of medical equipment.

British Columbia:

British Columbia Regulation 53/93, part 5/Miscellaneous states that: effective July 1, 1994, a person must not use Class I substances as a diluent for a gaseous sterilant. A person who contravenes the sterilant regulation is liable to a fine not exceeding $200,000.

Regarding sterilants, agreement has been reached between the B.C. government and hospitals to change to non-CFC or HCFC sterilization. Abtox has signed a contract to supply B.C. hospitals with 30 plasma-peracetic acid sterilization units. Funding is shared with the Province which provides 60% of the cost.

Manitoba:

Section 12(20) of the Manitoba regulation states that, after December 31, 1994, a person who uses a sterilant that contains a Class I substance as a gas carrier shall recover and recycle the Class I substance from the sterilant. Storage of recovered ODS is allowed if the condition or the quality of the substance is inadequate for recycling until destruction techniques for ODS are readily available.

The regulation does not take into consideration the phase-out dates of CFCs as set by the Montreal Protocol and the anticipated shortage of CFC supplies.

New Brunswick:

Among all provincial regulations, the New Brunswick regulation is the most specific one with respect to the use of CFCs in sterilants. Furthermore, the Province is strongly opposed to the nomination of sterilization as an essential use after 1995.

Under Section 32 of the Clean Environment Act, Regulation 92-119, Section 15(1) states that, effective October 4, 1992, no person shall install, offer for sale, sell, lease, supply or purchase equipment that contains, is intended to contain or is intended to operate, or operates using an ozone-depleting substance for the purpose of sterilizing medical equipment or of sterilizing any other thing, except a sterilization system that completely recovers the ODS; and,

Section 15(2): after December 31, 1993, no person shall use equipment for the purpose of sterilizing medical equipment or sterilizing any other thing, except in a sterilization system that completely recovers and recovers any ODS contained in or used by the equipment.

A 1991 survey of ODS use in N.B. showed that 6 out of 15 hospitals used 12/88 EO/CFC-12 sterilant, and an estimated 8780 kilograms of CFC-12 were released into the atmosphere.

The N.B. Department of Health and Community Services was to purchase fifteen 100% EO sterilization units. Shortage of funds was the main reason for not purchasing non-ODS sterilizers.

N.B. is currently amending its regulation to phase-out Class I substances in sterilants, and to allow the use of Class II substances until their ban in 2009.

Nova Scotia:

Nova Scotia Regulation 8/91 prohibits, effective July 1, 1991, the use of ozone-depleting substances in solvents, while refrigerants must be captured and recycled. Sterilization was not covered in the regulation.

Québec:

According to Québec's regulation, effective June 1993, any person who uses a gas sterilization apparatus shall recover the ozone-depleting substance released therefrom by using equipment designed to recover such substance.

In addition, any person who sells or distributes CFCs, HCFCs or halons must submit reports to the Minister by March 31 of each year describing the main sector of activity and the name and quantity of the substance sold or distributed.

Saskatchewan:

The list of ODS in the Saskatchewan regulation includes specific CFCs, HCFCs, halons and their isomers.

The regulation states that, on and after January 1, 1995, no person shall use an ozone-depleting substance to which the Act applies in sterilant gas mixtures, in-whole or in-part.

Prince Edward Island:

Prince Edward Island is currently developing a regulation for the control of ODS. The "Draft" regulation identifies the conditions of sale, labelling and sales records. "On or after January 1, 1995, no person shall make use of any product containing an ODS either alone or as a mixture for the purpose of:
a) Sterilization of medical equipment or the sterilization of anything, except in a system where the used gas sterilant is completely recovered and recycled".

Storage of ODS waste in approved cylinders is permitted if the condition of waste does not allow for its recycling until approved destruction techniques are readily available.

A summary of provincial regulations on sterilants is presented in Table 4.

Table 4: Provincial Regulations on STERILANTS

PROVINCE	Prohibitions	Exemptions
ALBERTA	- Sept. 1, 1993: general prohibition: Ozone-Depleting Substances be reclaimed, recycled and reused	sterilization of medical and health and animal care
BRITISH COLUMBIA	- Effective July 1, 1994, a person must not use a Class I substance as a diluent for a gaseous sterilant.	
MANITOBA	- after Dec. 31, 1994 a person who uses a sterilant that contains Class I substances as a gas carrier shall recover and recycle the Class I substance from the sterilant	- if CFCs are recovered and recycled; - storage allowed until destruction techniques are available.
NEW BRUNSWICK	- Sept. 16, 1992: install, offer for sale, sell, lease, supply or purchase equipment that contains or operates using ODS for sterilizing medical equipment or other things - Dec. 31, 1993, the use of equipment for purpose of sterilizing medical equipment or other things	- if the system completely recovers and recycles the ODS - if the system completely recovers and recycles the ODS
NOVA SCOTIA	Release of ODS is prohibited	
Prince Edward Island	Draft reg.: As of Jan. 1, 1995, ban use, make ODS-containing substance for sterilization purposes unless sterilant is recovered and recycled.	Storage of waste is allowed until disposal is available if condition of waste does not allow recycling.
QUÉBEC	- Apr. 1, 1995, any person who uses a gas sterilization apparatus shall recover the ozone-depleting substance released therefrom by using equipment designed to recover such substance.	- if ODS is recovered and recycled using proper equipment
SASKATCHEWAN	- Jan. 1, 1995, use of ODS in sterilant gas mixtures.	health care and animal use.

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